

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

ETHICON ENDO-SURGERY, INC.
4545 Creek Road
Cincinnati, OH 45242

Plaintiff,

v.

COVIDIEN, INC.
15 Hampshire Street
Mansfield, MA 02048

Serve Registered Agent:
CT Corporation System
1300 E. Ninth Street
Cleveland, OH 44114

Judge:

Civil Case No.: 1:11-cv-871

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Ethicon Endo-Surgery, Inc. ("EES") for its Complaint against Defendant Covidien, Inc. ("Covidien"), alleges as follows:

NATURE OF THE ACTION

1. This Complaint is an action for patent infringement and declaratory judgment of patent infringement of United States Patent No. 5,322,055 ("the '055 patent")(Exhibit A) under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*

2. This action arises out of Covidien's manufacture, use, and upcoming commercial launch of its Sonicision™ Cordless Ultrasonic Dissection Device ("Sonicision").

THE PARTIES

3. Plaintiff EES is a corporation organized under the laws of the State of Ohio, having its headquarters and principal place of business at 4545 Creek Road, Cincinnati, OH 45242.

4. On information and belief, Defendant Covidien is a corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 15 Hampshire Street, Mansfield, MA 02048.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. On information and belief, this Court has personal jurisdiction over Covidien because it has purposefully availed itself of the benefits and protections of Ohio's laws such that it should reasonably anticipate being haled into court here.

7. On information and belief, Covidien has had persistent and continuous contacts in the State of Ohio and within this judicial district, including by marketing, distributing, and selling medical devices, pharmaceuticals, and medical supplies in the State of Ohio and this judicial district (including sales to numerous medical facilities within this judicial district).

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

9. On information and belief, Covidien has used the accused Sonicision product within this judicial district.

10. On information and belief, in August 2011, Covidien representatives used Sonicision in a product demonstration at a facility (located within this judicial district) that is part of or associated with The Ohio State University.

11. On information and belief, at the demonstration referenced in paragraph 10, Covidien representatives allowed and encouraged physicians associated with The Ohio State University to use Sonicision.

12. On information and belief, at the demonstration referenced in paragraph 10, one or more physicians in attendance used Sonicision.

13. On information and belief, at some time after Sonicision was approved by the U.S. Food and Drug Administration ("FDA"), Covidien representatives used and/or encouraged third parties to use Sonicision in a mobile innovation truck (a tractor trailer) while the innovation truck was parked within this judicial district, including while parked in Cincinnati, OH.

14. On information and belief, third parties invited or encouraged by Covidien representatives used Sonicision within the mobile innovation truck, including while the truck was parked in this judicial district.

BACKGROUND

A. The Patent-In-Suit

15. EES is the owner by assignment of the '055 patent.

16. The '055 patent is titled "Clamp Coagulator/Cutting System For Ultrasonic Surgical Instruments." It issued on June 21, 1994 and has, *inter alia*, claims directed to ultrasonic surgical instruments for cutting, coagulating, grasping and blunt-dissecting tissue.

17. The '055 patent was reexamined in 1996 by the United States Patent and Trademark Office pursuant to a request by EES's parent company, Johnson & Johnson. As a result of the reexamination: (i) the patentability of claims 1, 2, 10, 15-17, 26, 31 and 42 of the '055 patent was confirmed without amendment, (ii) claims 3, 4, 11-14, 18, 24, 25, 27-30, 32, 33, 35, and 38-40 were determined to be patentable as amended, (iii) claims 5-9, 19-23, 34, 36, and 37, dependent on an amended claim, were deemed to be patentable, (iv) claim 41 was cancelled, and (v) claims 43-52 were added and determined to be patentable.

B. The Plaintiff

18. EES is a leading manufacturer of medical devices and surgical instruments. EES has been the leader in energy-based surgical devices since 1992, when it introduced ultrasonic technology.

19. EES currently markets numerous products under the HARMONIC® trademark, including the HARMONIC ACE® Curved Shears for laproscopic and open surgical procedures and UltraCision HARMONIC® Scalpel.

C. The Defendant and Accused Product

20. Covidien sells medical devices, pharmaceuticals, and medical supplies. Its product offerings include energy-based surgical devices.

21. In June 2010, Covidien submitted 510(k) Number K101797 to the FDA seeking approval to market Sonicision.

22. A 510(k) is an application/process by which a manufacturer seeks FDA approval to market a new medical device by demonstrating that the new device is substantially similar to a previously approved medical device.

23. In its 510(k) Number K101797, Covidien represented to the FDA that Sonicision was "substantially similar" to EES's UltraCision Harmonic Scalpel and Harmonic Ace Curved Shears with Hand Control.

24. A summary of Covidien's 510(k) Number K101797, available from the FDA at http://www.accessdata.fda.gov/cdrh_docs/pdf10/K101797.pdf and attached as Exhibit B, is excerpted below:

Predicate Devices

The Sonicision Cordless Ultrasonic Dissection Device described in this submission was compared and found to be substantially equivalent to the following ultrasonic surgical devices:

Device Name: Instrument, Ultrasonic, Scalpel
Trade Name [Model Number]: UltraCision Harmonic Scalpel [GEN4; HP054]
510(k) Number: K002906 (cleared 12/15/2000)
Manufacturer: Ethicon Endo-Surgery, Inc.

Device Name: Harmonic ACE Curved Shears with Hand Control
Model Number: ACE36E
510(k) Number: K042777 (cleared 12/1/2004); K060245 (cleared 4/7/2006)
Manufacturer: Ethicon Endo-Surgery, Inc.

25. Based on Covidien's 510(k) Number K101797, the FDA determined that Sonicision was "substantially equivalent" to EES's UltraCision Harmonic Scalpel and Harmonic Ace Curved Shears with Hand Control. *See* Exhibit B.

26. The FDA approved Sonicision for marketing on February 24, 2011 ("FDA Approval"). *See* Exhibit B.

27. On information and belief, in a publicly available earnings call on April 21, 2011, Covidien's then-CEO (and current Chairman of the Board) Richard Meelia stated that Covidien would begin selling Sonicision by the end of 2011.

28. On information and belief, Mr. Meelia specifically stated the following during the April 21, 2011 earnings call: "Perhaps, the most exciting news in Energy is our

Sonicision Cordless Ultrasonic Device that was FDA approved last month and will be launched later in 2011. This is our first foray into the \$800 million ultrasonic market. Sonicision will target general, bariatric, colorectal, urological and gynecological procedures. The addition of Sonicision not only broadens Covidien's portfolio of energy-based devices, it also gives customers one source for their advanced energy solutions, potentially offering savings from standardization. Both our electrosurgical and hardware products led by the ForceTriad energy system posted good quarterly growth. Energy hardware sales were at their highest level since the fourth quarter of 2008 indicating a positive shift in capital equipment purchases by hospitals."

29. On information and belief, Covidien will not launch Sonicision in 2011, but now intends to begin selling the product in 2012.

30. On information and belief, Covidien intends to begin selling Sonicision in the first calendar quarter of 2012.

31. On information and belief, Covidien has manufactured Sonicision in the United States or imported Sonicision into the United States for product demonstration purposes.

32. On information and belief, Covidien has taken substantial steps, beyond obtaining FDA Approval, to begin selling Sonicision.

33. On information and belief, these substantial steps include Sonicision demonstrations in the United States and discussions with physicians about the product.

34. On information and belief, Covidien representatives have used and demonstrated Sonicision in the United States multiple times following FDA Approval.

35. On information and belief, Covidien representatives have allowed or encouraged others to use Sonicision during product demonstrations in the United States following FDA Approval.

36. On information and belief, in August 2011, Covidien representatives used Sonicision in a product demonstration in this judicial district at a facility that is part of or associated with The Ohio State University.

37. On information and belief, at the demonstration referenced in paragraph 37, Covidien representatives encouraged and allowed physicians associated with The Ohio State University to use Sonicision.

38. On information and belief, one or more physicians in attendance at the demonstration used Sonicision.

39. On information and belief, at some time after FDA Approval, Covidien representatives demonstrated and/or encouraged third parties to use Sonicision in a mobile innovation truck, including demonstrations while the innovation truck was parked in Cincinnati, OH.

40. On information and belief, third parties invited or encouraged by Covidien representatives used Sonicision within the mobile innovation truck, including while the truck was parked in this judicial district.

41. The activities alleged in paragraphs 31 to 40 are not covered under the safe harbor provisions of 35 U.S.C. § 271(e)(1) or any other safe harbor provision to patent infringement under U.S. laws.

42. On information and belief, Covidien was aware that Sonicision infringed the '055 patent by at least August 24, 2011.

COUNT I
PATENT INFRINGEMENT
(Direct Infringement)

43. EES repeats and realleges each and every allegation contained in paragraphs 1 through 42 hereof, as if fully set forth herein.

44. Covidien has infringed the '055 patent, including at least claim 1, by making and using Sonicision in the United States and/or importing Sonicision to the United States.

45. EES has been, and continues to be, damaged by Covidien's infringement of the '055 patent.

46. On information and belief, Covidien's infringement has been willful because it is aware that Sonicision infringes the '055 patent, yet continues with its infringing activities.

47. Covidien's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

COUNT II
PATENT INFRINGEMENT
(Inducement To Infringe)

48. EES repeats and realleges each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

49. Covidien has infringed the '055 patent, including at least claim 1, by intentionally inducing infringement by others through encouraging use of Sonicision in product demonstrations despite knowledge that the use of Sonicision infringes the '055 patent.

50. EES has been, and continues to be, damaged by Covidien's inducement to infringe the '055 patent.

51. On information and belief, Covidien's inducement has been willful because it is aware that Sonicision infringes the '055 patent, yet continues with its infringing activities.

52. Covidien's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

COUNT III
DECLARATORY JUDGEMENT

53. EES repeats and realleges each and every allegation contained in paragraphs 1 through 52 hereof, as if fully set forth herein.

54. On information and belief, Covidien has taken substantial steps in preparation to commercially launch Sonicision. These preparatory actions include obtaining FDA approval to market Sonicision, notifying the public of the upcoming launch, and performing product demonstrations throughout the United States.

55. On information and belief, Covidien is not changing its course regarding its plans to commercially launch Sonicision despite knowledge of the '055 patent.

56. Covidien's currently infringing activities (as set forth in Counts I and II), preparatory actions for launch, and refusal to change course regarding its launch plans place EES under a reasonable apprehension that Covidien will infringe the '055 patent, including at least claim 1, upon Sonicision's launch through its manufacture, use, importation, offer for sale, and/or sale of Sonicision.

57. EES will be damaged by Covidien's infringement of the '055 patent.

58. There now exists a justiciable case and controversy for adjudication of this declaratory judgment count by the Court.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

- (a) a judgment that Covidien has infringed the '055 patent;
- (b) a permanent injunction prohibiting Covidien from infringing the '055 patent;
- (c) an award of damages adequate to compensate EES for Covidien's infringement of the '055 patent, including damages and/or other monetary relief pursuant to 35 U.S.C. § 284 for (i) Covidien's infringing manufacture, use, and/or importation of Sonicision and (ii) infringement in the event Covidien offers for sale or sells surgical apparatus falling within the scope of one or more claims of the '055 patent;
- (d) an award of EES's interest, costs, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 285; and,
- (e) a declaration that Covidien's offer for sale and sale of Sonicision will infringe the '055 patent; and
- (f) such other and further relief as the Court may deem just and proper.

Dated: December 14, 2011

Respectfully submitted,

s/David E. Schmit

David E. Schmit (0021147)
FROST BROWN TODD LLC
3300 Great American Tower
301 East Fourth Street
Cincinnati, OH 45202
Tel.: (513) 651-6800
Fax.: (513) 651-6981
dschmit@fbtlaw.com

Attorney for Ethicon Endo-Surgery, Inc.

Of Counsel:

William F. Cavanaugh Jr.

Chad J. Peterman

Charles D. Hoffman

PATTERSON BELKNAP

WEBB & TYLER LLP

1133 Avenue of the Americas

New York, NY 10036

Tel.: (212) 336-2000

Fax: (212) 336-2222

wfcavanaugh@pbwt.com

cjpeterman@pbwt.com

choffmann@pbwt.com

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